

REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1-2, 4-8, 10-13, 15-35, and 37-39 are pending with entry of this amendment, claims 6, 24-29 and 37-39 being withdrawn for future consideration by the Examiner.

Claims 3, 9 and 14 are cancelled herein. Cancellation of these claims is without prejudice, without intent to abandon any originally-claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications containing these cancelled claims.

Claims 1, 2, 4, 18 and 19 are amended herein. These amendments introduce no new matter and support is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record. Applicant submits that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

Objections to the Specification

Applicant has amended the specification to address the browser-executable code as helpfully pointed out by the Examiner.

35 U.S.C. §112, First Paragraph

Claims 1-5, 7-23 and 30-35 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicant traverses to the extent that the rejection applies to the amended claims.

To be an enabling disclosure under 35 U.S.C. §112, first paragraph, a patent must contain a description that enables one skilled in the art to make and use the claimed invention. That some experimentation is necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive. See In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The Office Action alleges that the specification is not enabled since undue experimentation is required in order to obtain cell lines and compositions having identical activities. Applicant has amended the claims to further clarify the claimed invention with respect to the "activities" of the compositions and cell lines, as helpfully suggested by the Examiner. The amended

claims are directed towards methods for identifying new compositions having a desired activity (with respect to a selected disease area of interest) comprising the steps of: providing a first set of compositions capable of causing a first demonstrated therapeutic activity, wherein at least one member of the first set of compositions is capable of causing a second desired activity related to a different disease area of interest; determining a genetic response profile for each member composition of the first set of compositions by a) providing a plurality of cell lines, wherein the plurality of cell lines comprises at least one modified cell line which differs from a corresponding parent cell line in at least one selected protein or nucleic acid; b) treating each member of the plurality of cell lines with each member composition of the first set of compositions; and c) detecting an activity or concentration of the selected protein or nucleic acid in response to the member compositions; correlating the one or more responses from the genetic response profile to the first demonstrated therapeutic activity and second desired activity caused by each member composition, thereby identifying a pattern of responses correlating to a decrease in the first demonstrated therapeutic activity and an increase in the second desired activity; and screening a second set of compositions for the pattern of responses, thereby identifying a new composition capable of causing the second desired activity.

Applicant respectfully submits that the specification teaches one of skill how to make and use the claimed invention without undue experimentation, and respectfully requests that the rejection under 35 USC §112, first paragraph be withdrawn.

35 U.S.C. §103(a)

Applicant notes that the rejection of claims 1-4, 7-21, 26 and 33-35 under 35 U.S.C. §103(a) as allegedly unpatentable over Vande Woude et al (USPN 5,645,988) was withdrawn in light of the rejection under §112, first paragraph. Should the rejection be reinstated, Applicant submits that the claims as amended are patentable over Vande Woude.

A *prima facie* case of obviousness requires that the cited art, taken with the general knowledge in the field, must provide all of the elements of the claimed invention. As noted above, claim 1 is drawn to methods of identifying new compositions with a desired activity, based upon patterns within genetic response profiles correlating to a decrease in the first demonstrated therapeutic activity and an increase in the second desired activity. Vande Woude is alleged to teach a method of identifying a drug having a specified activity (selective inhibition of growth of particular cancer cells) using cancer cell lines. However, the cited art does not provide all of the elements of the claimed

invention. For example, Vande Woude does not teach or disclose comparing one or more responses from a genetic response profile to both the first demonstrated activity and second desired activity evoked by each member composition. Nor does Vande Woude teach or disclose identifying a pattern of responses that correlate to a decrease in the first demonstrated activity and an increase in the second desired activity. Since the cited art does not teach all of the limitations of the claimed invention, the first criteria for a *prima facie* case of obviousness has not been met. Applicant respectfully submits that the claims are patentable over Vande Woude.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 337-7871 to schedule an interview.

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Respectfully submitted,



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Attachments:

- 1) A petition to extend the period of response for **2** months;
- 2) A transmittal sheet;
- 3) A fee transmittal sheet; and,
- 4) A receipt indication postcard.